AUG 2 0 2003

510(K) SUMMARY

Duet™ system

510(k) Number K 030192

Applicant's Name:

Bioview Ltd.
12 Hamada Street,
Rehovot 76703, Israel
Tel: 972-8-9366868
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Contact Person:

Orly Maor
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
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orly@push-med.com

Date Prepared:

January, 2003

Trade Name:

Duet™ system

Classification Name:

Automated cell-location device

Classification:

The FDA has classified Automated cell-locating device as class II devices (product code 81 JOY, Regulation No. 864.5260) and they are reviewed by the Pathology Panel.

Predicate Device:

- SlideScan™, manufactured by Applied Imaging, Inc., cleared under K001420.
- ACIS (Automated Cellular Imaging System), manufactured by CromaVision Medical Systems, Inc. cleared under K984188.
- BandView, manufactured by Applied Spectral Imaging, cleared under K012103.
- Human manual visualization by conventional microscope.

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the Duet™ system complies with the following voluntary standards:

- EN 61010-1
- EN 61326-1
- IEC 60601-1-4
- EN-1441: Medical devices – Risk Analysis.
- ISO 14971 Medical Devices-Risk Management

Indications:

The Duet™ system is an automated scanning microscope and image analysis system. It is intended for in-vitro diagnosis use as an aiding tool to the pathologist in the detection, classification and counting of cells of interests based on particular color, intensity, size, pattern and shape.

This particular application is intended to detect hematopoietic cells positively stained by Giemza stain, Immunohistochemistry or ISH (with bright field and fluorescent) prepared from cell suspension. The device can be used without limitation to specific diseases.

Device Description:

The Duet™ System is a fully integrated imaging and scanning platform that automates time-consuming and difficult laboratory tasks of slide screening by making a significant reduction in time and labor currently required.

The Duet™ scans in high resolution and in full color cell samples at high speed both in bright light illumination and in fluorescent illumination.
Duet™ suggests classification of the cells according to their morphological features, their staining (Giemsa, IHC) and fluorescent signals, and allows the user to quickly examine the results, correct them as needed and generate a report summarizing the sample's data. The unique feature of the Duet system allows the presents combined presentation of morphological and specific staining information of the same cell, for all the cells of the sample.

Substantial Equivalence:

Bioview Ltd. believes that the Duet™ system is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Bioview Limited
c/o Mr. Orly Maor
Push-Med Limited
117 Ahuzah Street
Ra'ananna 43373
ISRAEL

AUG 2 0 2003

Re: k030192
Trade/Device Name: *Duet*™ System
Regulation Number: 21 CFR § 864.5260
Regulation Name: Automated cell-location device
Regulatory Class: II
Product Code: JOY
Dated: July 7, 2003
Received: July 9, 2003

Dear Mr. Maor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K030192

Device Name: Duet™ system

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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K030192

510(k) Number _____

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)